

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE ORAL SODIUM PHOSPHATE  
SOLUTION-BASED PRODUCTS  
LIABILITY LITIGATION**

**CASE NO: 1:09-SP-80000,  
(MDL DOCKET NO. 2066)**

**THE HONORABLE ANN ALDRICH**

**THIS DOCUMENT RELATES TO:  
ALL ACTIONS**

**MASTER ANSWER AND AFFIRMATIVE DEFENSES**

Defendant C.B. Fleet Company, Inc. ("Fleet") for its Answer to Plaintiffs'

Master Consolidated Complaint for Individuals ("Complaint"), responds as follows:

**PARTIES**

1. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in paragraph 1 of Plaintiffs' Complaint, except admits that it marketed three separate products known as Fleet® Phospho-soda®, Fleet® Phospho-soda® Accu-Prep™ and Fleet® Phospho-soda® EZ-Prep™.

2. Admitted.

**JURISDICTION AND VENUE**

3. Fleet admits only that it is a Virginia corporation with its principal place of business in Virginia, but is without knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint. Therefore, Fleet denies these remaining allegations.

4. Fleet admits that venue in this judicial district is proper for coordination and pre-trial purposes pursuant to the Transfer Order of the United States Judicial Panel on

Multidistrict Litigation, entered on June 23, 2009. Fleet also admits that it has stipulated to the propriety of this venue for any case filed directly into this MDL in accordance with Case Management Order No. 1. The remaining allegations contained in Paragraph 4 of Plaintiff's Complaint constitute conclusions of law to which no response is required.

5. Fleet admits that at certain times not specifically set forth in Plaintiffs' Complaint, Fleet manufactured, marketed, distributed and sold a pharmaceutical product known as Fleet® Phospho-Soda® ("Phospho-soda") as an over-the-counter product for the use as a laxative in accordance with all laws and regulations. By way of further answer, Phospho-Soda was also lawfully sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures only upon the prescription or direction of a duly licensed physician.

#### **COMMON FACTUAL ALLEGATIONS**

6. Fleet denies the allegations contained in Paragraph 6 of Plaintiffs' Complaint except admits that Phospho-soda is an oral sodium phosphate solution-based ("OSPS") product that was sold as an over-the-counter product for use as a laxative for relief of occasional constipation; Phospho-Soda was sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures only upon the prescription or direction of a duly licensed physician in accordance with the warnings and other information contained in the professional use labeling available to physicians.

7. Admitted.

8. Fleet denies the allegations contained in Paragraph 8 of Plaintiffs' Complaint, except admits that 45 mL of Phospho-Soda contains 8.1 grams of diacidic sodium phosphate heptahydrate and 21.6 grams of monobasic sodium phosphate monohydrate.

9. Fleet denies the allegations contained in Paragraph 9 of Plaintiffs’

Complaint, except admits that at certain times not specifically set forth in Plaintiffs’ Complaint, that the Tentative Final Monograph (“TFM”) for laxative drug products provided that the “oral dosage” for adults and children over 12 years of age is sodium phosphate 3.42 to 7.56 grams, and sodium biphosphate 9.1 to 20.2 grams in a single daily dose, which was modified by Final Rule dated May 21, 1998 to include the following language: “Do not take more unless directed by a doctor. See warnings.”

10. Fleet denies the allegations contained in Paragraph 10 of Plaintiffs’

Complaint, except admits that at certain times not specifically set forth in Plaintiffs’ Complaint, Phospho-soda was sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures including a colonoscopy, only upon the prescription or direction of a duly licensed physician and dosing and timing instructions were prescribed and/or directed by a duly licensed physician in accordance his or her medical judgment and with warnings and other information in the professional use labeling available to physicians. Any characterization of the product warning that is inconsistent with the product labeling or professional use labeling is denied.

11. Fleet denies the allegations contained in Paragraph 11 of Plaintiffs’

Complaint, except admits only that 90 mL of Phospho-soda contains 16.2 grams of dibasic sodium phosphate heptahydrate and 43.2 grams of monobasic sodium phosphate monohydrate. By way of further answer, the TFM did not specifically limit the professional use of sodium phosphates as part of a bowel cleansing regimen. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

12. Fleet denies the allegations contained in the Paragraph 12 of Plaintiffs' Complaint, except admits that in June 2003 it submitted a Citizen's Petition requesting that the United States Food and Drug Administration ("FDA") modify the TFM to include professional labeling for 2 x 30 mL to 2 x 45 mL dosing of Phospho-soda administered 10-12 hours apart.

13. Fleet specifically denies that it publicized, promoted and recommended any dosing regimen to consumers regarding the use of Phospho-soda in a bowel cleaning regimen. Fleet admits that at certain times not specified in Plaintiffs' Complaint, and in accordance with the warnings and other information contained in the professional use labeling available to physicians, it recommended to physicians the use of two 45 mL doses of Phospho-soda, separated by 10 to 12 hours, as a safe and effective bowel cleansing regimen.

14. Fleet denies the allegations contained in Paragraph 14 of Plaintiffs' Complaint except admits that on December 11, 2008, the FDA responded to Fleet's Citizen Petition dated June 25, 2003, which being a writing speaks for itself. Any inconsistent characterizations of the FDA's December 11, 2008 actions are denied.

15. Fleet denies the allegations contained in Paragraph 15 of Plaintiffs' Complaint except admits that the FDA responded to Fleet's Citizen's Petition on December 11, 2008, which being a writing speaks for itself. Any inconsistent characterizations of the FDA's December 11, 2008 actions are denied.

16. Fleet denies the allegations contained in Paragraph 16 of Plaintiffs' Complaint except admits that on December 11, 2008, the FDA responded to Fleet's Citizen Petition dated June 25, 2003. The FDA's December 11, 2008 response to the Citizen Petition,

being a writing, speaks for itself. Any inconsistent characterizations of the FDA's December 11, 2008 actions are denied.

17. Fleet denies the allegations contained in Paragraph 17 of Plaintiffs' Complaint, except admits that Fleet, in response to a FDA safety alert, issued a voluntary recall of its over-the-counter Phospho-soda products directed toward retailers and wholesalers.

18. The allegations contained in the Paragraph 18 of Plaintiffs' Complaint are denied except that Fleet admits it received rare reports of serious injury following use of Phospho-soda mainly in contraindicated or overdosed patients. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

19. Fleet admits only that Phospho-soda may be associated with certain conditions and/or risks as set forth in the professional use labeling. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

20. Fleet denies the allegations contained in Paragraph 20 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

21. Fleet denies the allegations contained in Paragraph 21 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

22. Fleet denies the allegations contained in Paragraph 22 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

23. The allegations of Paragraph 23 constitute conclusions of law to which no response is required.

24. Fleet denies the allegations contained in Paragraph 24 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates its responses to Paragraphs 6 and 10.

25. Fleet denies the allegations contained in Paragraph 25 of Plaintiffs' Complaint. By way of further answer, on numerous occasions before December 11, 2008, Fleet updated its professional use warnings published in the *Physician Desk Reference* ("PDF") to reflect the most current and scientifically verified information that was known to it.

26. Fleet denies the allegations contained in Paragraph 26 of Plaintiffs' Complaint, except admit that at certain times not specifically set forth in Plaintiffs' Complaint that the professional use labeling for Phospho-soda as published in the PDR referenced medical literature relating to the professional use of Phospho-soda as a bowel cleanser, which, being writings, speak for themselves. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

27. Fleet denies the allegations contained in Paragraph 27 of Plaintiffs' Complaint.

28. Fleet denies the allegations contained in Paragraph 29 of Plaintiffs' Complaint.

29. Fleet denies the allegations contained in Paragraph 28 of Plaintiffs' Complaint. By way of further answer, Fleet states that its professional use labeling first published in the 2004 PDR included the recommendation that physicians consider using lower doses of Phospho-soda in certain patients. The PDR entries, being writings, speak for themselves and any inconsistent characterization of them is denied."

30. Fleet denies the allegations contained in Paragraph 30 of Plaintiffs' Complaint, except admits that Fleet ACCU-PREP™ contained a total of six 15 mL doses, for a total of 90 mL of Phospho-soda in the ACCU-PREP™ package.

31. Fleet denies the allegations contained in Paragraph 31 of Plaintiffs' Complaint, except admits that EZ-PREP™ contains, among other things, two premeasured doses (one 45mL dose and one 30mL dose) of Phospho-soda which Fleet recommends to physicians that they prescribe each dose be taken at least 10 to 12 hours apart.

32. Fleet denies the allegations contained in Paragraph 32 of Plaintiffs' Complaint. By way of further answer, the active ingredients and excipients of Phospho-soda are each characterized by slow and incomplete absorption into the blood stream from the gastrointestinal tract.

33. Fleet denies the allegations contained in Paragraph 33 of Plaintiffs' Complaint except admits that Phospho-soda may be associated with certain conditions and/or risks as set forth in the professional use labeling. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10 and 25.

34. Fleet admits only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in Paragraph 34 are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and Fleet incorporates its responses to Paragraphs 6, 10 and 25.

35. Fleet admits only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in Paragraph 35 are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and Fleet incorporates its responses to Paragraphs 6, 10 and 25.

36. Fleet admits only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in Paragraph 36 are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and Fleet incorporates its responses to Paragraphs 6, 10 and 25.

37. Fleet denies the allegations contained in Paragraph 37 of Plaintiffs' Complaint, except admits that hydration recommendations are set forth in the professional use labeling and have been modified over time to emphasize the importance of hydration when the product is used. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

38. It is admitted only that Fleet had never conducted a study where the minimum amount of liquid necessary for a safe and effective bowel cleansing regimen has been the primary endpoint. By way of further answer, Fleet has conducted clinical studies in which hydration status in connection with bowel cleansing has been studied.

39. Fleet denies the allegations contained in Paragraph 39 of Plaintiffs' Complaint.



40. Fleet denies the allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Fleet denies the allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Fleet denies the allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Fleet denies the allegations contained in Paragraph 43 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

44. Fleet denies the allegations contained in Paragraph 44 of Plaintiffs' Complaint, except admits that at certain times not specifically set forth in Plaintiffs' Complaint the 1.5 ounce package of Phospho-soda stated "[w]hen taken as directed, laxative action is gentle, virtually free from the likelihood of gastrointestinal discomfort or irritation, and is safe for the age groups indicated." It is further denied that Fleet made any express representations to Plaintiffs in connection with the use of the product as a bowel cleanser. Fleet is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 44 regarding the allegation that any plaintiff was in any particular age group at the time he or she allegedly used the product. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

45. Fleet is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 45 regarding to the allegation that any plaintiff was in any particular age group at the time he or she allegedly used the product.

46. The allegations contained in Paragraph 46 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual, they are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

47. The allegations contained in Paragraph 47 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

48. Fleet denies the allegations contained in Paragraph 48 of Plaintiffs' Complaint concerning any "false representations and omissions regarding the safety of the Double Dose of Fleet Phospho-soda and the dangers and health risks associated with the product." By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

49. The allegations contained in Paragraph 46 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent that the allegations are factual, they are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, and 25.

50. Fleet denies the allegations contained in Paragraph 50 of Plaintiffs' Complaint that Fleet made misrepresentations concerning Phospho-soda. Fleet is without knowledge or information sufficient to form a belief as to the remaining allegations with respect

to plaintiffs' alleged beliefs and reliance. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10 and 25.

51. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Fleet denies the allegations contained in Paragraph 52 of Plaintiff's Complaint. By way of further answer, Fleet states that at all relevant times, consumers were directed to consult with their physician before using Phospho-soda in greater than laxative dosing, and that following the development of a patient information sheet acceptable to the FDA, such a patient information sheet was included in the consumer packaging of Phospho-soda. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10 and 25.

53. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations as to how plaintiffs actually used the product. The remaining factual allegations of Paragraph 53 are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25, and 52.

54. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations as to the plaintiffs' use of the product. The remaining factual allegations of Paragraph 54 are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25, and 52.

55. The allegations contained in Paragraph 55 of Plaintiffs' Complaint constitute legal conclusions to which no response is required. To the extent the allegations are

factual, they are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25 and 52.

56. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in Paragraph 56 of Plaintiffs' Complaint.

57. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. The allegations contained in Paragraph 58 of Plaintiffs' Complaint constitute conclusion of law to which no response is required. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations as they pertain to plaintiffs' alleged injuries or damages.

59. The allegations contained in Paragraph 59 of Plaintiffs' Complaint contain conclusions of law to which no response is required. To the extent that the allegations are factual, they are denied. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25 and 52.

60. Fleet denies the allegations contained in Paragraph 60 of Plaintiffs' Complaint except admits that Fleet expected the packaging and contents would reach consumers without substantial change in form or condition. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25 and 52.

61. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in Paragraph 61 of Plaintiffs' Complaint.

**FIRST CAUSE OF ACTION**  
(Strict Liability – Failure to Warn)

62. In response to Paragraph 62 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 61 of its Answer above as fully rewritten herein.

63. The allegations contained in Paragraph 63 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

64. The allegations contained in Paragraph 64 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

65. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in Paragraph 65 of Plaintiffs' Complaint with respect to the plaintiffs' alleged injuries or damages.

66. The allegations contained in Paragraph 66 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

67. The allegations contained in Paragraph 67 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual, they are denied.

**SECOND CAUSE OF ACTION**  
(Strict Liability – Design Defect)

68. In response to Paragraph 68 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 67 of its Answer above as fully rewritten herein.

69. The allegations contained in Paragraph 69 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

70. Fleet denies the allegations contained in Paragraph 70 of Plaintiffs' Complaint. By way of further answer, Fleet incorporates by reference its response to Paragraph 34.

71. Fleet denies the allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. The allegations contained in Paragraph 72 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual they are denied.

73. Fleet denies the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. The allegations contained in Paragraph 74 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual they are denied.

75. The allegations contained in Paragraph 75 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

76. The allegations contained in Paragraph 76 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or

information sufficient to form a belief as to the truth or accuracy of the allegations pertaining to plaintiffs' alleged injuries or damages.

**THIRD CAUSE OF ACTION**

(Negligence)

77. In response to Paragraph 77 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 76 of its Answer above as fully rewritten herein.

78. The allegations contained in Paragraph 78 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25 and 52.

79. The allegations contained in Paragraph 79 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

80. The allegations contained in Paragraph 80 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

81. The allegations contained in Paragraph 81 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged injuries or damages

82. The allegations contained in Paragraph 82 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

**FOURTH CAUSE OF ACTION**

(Misrepresentation/Consumer Fraud)

83. In response to Paragraph 83 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 82 of its Answer above as fully rewritten herein.

84. The allegations contained in Paragraph 84 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

85. The allegations contained in Paragraph 85 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

86. The allegations contained in Paragraph 86 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged injuries or damages.

87. The allegations contained in Paragraph 87 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

88. The allegations contained in Paragraph 88 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

**FIFTH CAUSE OF ACTION**  
(Breach of Express Warranties)

89. In response to Paragraph 89 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 88 of its Answer above as fully rewritten herein.

90. Fleet denies the allegations contained in Paragraph 90 of Plaintiffs' Complaint.



91. The allegations contained in Paragraph 91 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. By way of further answer, Fleet incorporates its responses to Paragraphs 6, 10, 25 and 52.

92. The allegations contained in Paragraph 92 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent that the allegations are factual, they are denied.

93. The allegations contained in Paragraph 93 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged injuries or damages

**SIXTH CAUSE OF ACTION**  
(Breach of Express Warranties)

94. In response to Paragraph 94 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 93 of its Answer above as fully rewritten herein.

95. The allegations contained in Paragraph 95 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

96. The allegations contained in Paragraph 96 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

97. The allegations contained in Paragraph 97 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or

information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged injuries or damages.

**SEVENTH CAUSE OF ACTION**  
(Fraud & Deceit)

98. In response to Paragraph 98 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 97 of its Answer above as fully rewritten herein.

99. The allegations contained in Paragraph 99 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual, they are denied. By way of further answer, Fleet incorporates by reference its responses to Paragraphs 6, 10, 25 and 52.

100. The allegations contained in Paragraph 100 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations are factual, they are denied. By way of further answer, Fleet incorporates by reference its responses to Paragraphs 6, 10, 25 and 52.

101. The allegations contained in Paragraph 101 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

102. The allegations contained in Paragraph 102 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. To the extent the allegations to representations made or omitted by Fleet, they are denied. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged beliefs or reliance.

103. The allegations contained in Paragraph 103 of Plaintiffs' Complaint constitute conclusions of law to which no response is required. Fleet is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations with respect to the plaintiffs' alleged injuries or damages

104. Fleet denies the allegations contained in Paragraph 104 of Plaintiffs' Complaint.

105. The allegations contained in Paragraph 105 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

**EIGHTH CAUSE OF ACTION**  
(Loss of Consortium)

106. In response to Paragraph 106 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 105 of its Answer above as fully rewritten herein.

107. Fleet denies the allegations contained in Paragraph 107 of Plaintiffs' Complaint.

**NINTH CAUSE OF ACTION**  
(Wrongful Death)

108. In response to Paragraph 108 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 107 of its Answer above as fully rewritten herein.

109. Fleet denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 109 of Plaintiffs' Complaint regarding whether or how an

individual plaintiff ingested Phospho-soda. Fleet denies the allegation that any plaintiff died as a result of ingesting Phospho-soda. The remaining allegations contained in Paragraph 109 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

110. Fleet denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 110 of Plaintiffs' Complaint relating to whether an individual plaintiff has surviving family members. The remaining allegations contained in Paragraph 109 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

111. The allegations contained in Paragraph 111 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

112. Fleet denies the allegations contained in Paragraph 112 of Plaintiffs' Complaint.

**TENTH CAUSE OF ACTION**  
(Survival Action)

113. In response to Paragraph 113 of Plaintiffs' Complaint, Fleet incorporates by reference its responses in Paragraphs 1 through 112 of its Answer above as fully rewritten herein.

114. Fleet denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 114 of Plaintiffs' Complaint regarding whether or how an individual plaintiff ingested Phospho-soda. Fleet denies the allegation that any plaintiff died as a result of ingesting Phospho-soda. The remaining allegations contained in Paragraph 114 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

115. Fleet denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 115 of Plaintiffs' Complaint regarding whether an individual plaintiff ingested Phospho-soda. Fleet denies the allegation that any plaintiff died as a result of ingesting Phospho-soda. The remaining allegations contained in Paragraph 115 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

116. The allegations contained in Paragraph 116 of Plaintiffs' Complaint constitute conclusions of law to which no response is required.

**FIRST AFFIRMATIVE DEFENSE**

**Failure to State a Claim**

117. Plaintiffs' Complaint fails, either in whole or in part, to state a claim upon which relief can be granted against Fleet.

**SECOND AFFIRMATIVE DEFENSE**

**Failure to Mitigate**

118. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to adequately and appropriately mitigate the alleged damages.

**THIRD AFFIRMATIVE DEFENSE**

**Comparative Fault and/or Negligence**

119. Plaintiffs' claims are barred, in whole or in part, by the doctrines of comparative fault and/or negligence.

**FOURTH AFFIRMATIVE DEFENSE**

**Assumption of Risk**

120. Plaintiffs' claims are barred, in whole or in part, by the doctrine of assumption of risk.

**FIFTH AFFIRMATIVE DEFENSE**  
**Nonforeseeable Misuse**

121. Plaintiffs' claims are barred, in whole or in part, by the doctrine of nonforeseeable misuse.

**SIXTH AFFIRMATIVE DEFENSE**  
**State of the Art**

122. Plaintiffs' claims are barred, in whole or in part, by the state of the art and state of scientific knowledge doctrines.

**SEVENTH AFFIRMATIVE DEFENSE**  
**Inherent Product Aspect**

123. Plaintiffs' damages, if any, were caused by an inherent characteristic of the subject product that is a generic aspect of the subject product that cannot be eliminated without substantially compromising the subject product's usefulness or desirability.

**EIGHTH AFFIRMATIVE DEFENSE**  
**Collateral Source Doctrine**

124. Plaintiffs' recovery is limited by any recovery that Plaintiffs have received from collateral sources.

**NINTH AFFIRMATIVE DEFENSE**  
**Preemption**

125. Plaintiffs' claims are barred, in whole or in part, to the extent that the United States Food and Drug Administration required the use of professional labeling and restricted professional use warnings with regard to the consumer packaging and labeling.

**TENTH AFFIRMATIVE DEFENSE**  
**Intervening/Superseding Cause**

126. Plaintiffs' claims are barred, in whole or in part, by the doctrines of intervening and/or supervening cause.

**ELEVENTH AFFIRMATIVE DEFENSE**  
**Learned Intermediary Doctrine**

127. Plaintiffs' claims are barred, in whole or in part, by the learned intermediary doctrine.

**TWELFTH AFFIRMATIVE DEFENSE**  
**Laches, Waiver and Estoppel**

128. Discovery may show that Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, wavier and estoppel.

**THIRTEENTH AFFIRMATIVE DEFENSE**  
**Acts of Third Parties**

129. Plaintiffs' claims are barred, in whole or in part, by the intervening and/or supervening acts of third parties.

**FOURTEENTH AFFIRMATIVE DEFENSE**  
**Sophisticated User**

130. Plaintiffs' physicians and other medical care providers and plaintiffs' physicians' agents, servants, and employees, were sophisticated users of the subject product and possessed adequate information concerning warnings, precautions, and potential complications for those physicians and other medical care providers to assess the risks versus the benefits of the subject product before they prescribed it. Therefore, Plaintiffs' claims against Fleet are barred.

**FIFTEENTH AFFIRMATIVE DEFENSE**  
**Non-Economic Loss Limitations**

131. Plaintiffs' damages claim, if any, for non-economic losses is limited by the applicable governing doctrine.

**SIXTEENTH AFFIRMATIVE DEFENSE**  
**Informed Consent**

132. Plaintiffs' claims are barred, in whole or in part, by the doctrine of informed consent and release.

**SEVENTEENTH AFFIRMATIVE DEFENSE**  
**Defenses of Others**

133. Fleet incorporates the defenses of all others who may become parties to this action as though more fully set forth herein.

**EIGHTEENTH AFFIRMATIVE DEFENSE**  
**Statute of Limitations**

134. Discovery may show that Plaintiffs' claims are barred by the applicable statute(s) of limitations.

**NINETEENTH AFFIRMATIVE DEFENSE**  
**Operation of Nature**

135. Plaintiffs' alleged injuries, if any, were not the result of any act or omission on the part of Fleet, but exist by reason of operation of nature or idiosyncratic or allergic reaction, over which Fleet had no control.



**TWENTIETH AFFIRMATIVE DEFENSE**  
**Preexisting Condition**

136. Plaintiffs' alleged injuries, if any, are barred or limited by virtue of the fact that the injuries asserted are due to a preexisting condition and are not the result of the use of Fleet Phospho-Soda.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**  
**Not Unreasonably Dangerous**

137. Plaintiffs' claims are barred, in whole or in part, because, pursuant to Restatement (Second) of Torts, section 402A and comments thereto and/or the Restatement (Third) of Torts, sections 2, 4 and 6 and comments thereto, the product is not unreasonably dangerous given that the product was accompanied by proper directions and adequate warnings.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**  
**Nonforeseeable Injury**

138. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' injuries were not reasonably foreseeable.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**  
**Nonforeseeable User**

139. Discovery may show that Plaintiffs' claims are barred, in whole or in part, because Plaintiffs were not foreseeable users of Fleet Phospho-Soda.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**  
**Risks vs. Benefits**

140. Plaintiffs' claims are barred, in whole or in part, because the benefits of the product at issue outweighed the risks, if any, that may be associated with the product.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

**Proximate Cause**

141. Plaintiffs' claims are barred, in whole or in part, because if Plaintiffs were injured as alleged in the Complaint, any alleged failure to provide proper or adequate warnings, instructions and labeling by Fleet, assuming Fleet had such a duty, was not the proximate cause of such injuries.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

**Failure to Plead Misrepresentation/Fraud with Particularity**

142. Plaintiffs' misrepresentation and fraud and deceit claims are barred by the failure to plead the necessary elements of these claims with particularity.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

**Breach of Warranty Claims Barred**

143. Fleet did not make to Plaintiffs nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by the applicable law, the learned intermediary doctrine, lack of privity with Fleet, and/or failure of Plaintiffs to give timely notice to Fleet of any alleged breach of warranty. Fleet further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future, as enacted in the states whose law is deemed to apply in these cases.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

**Failure to State a Claim for Punitive Damages**

144. Any claims for punitive damages contained in Plaintiffs' Complaint, fail to state a claim upon which relief may be granted, violate various provisions of the Constitutions

of the United States and/or the Constitution of the state whose law is deemed to apply, and violate various statutory proscriptions thereof.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**  
**Limitation of Punitive Award**

145. With respect to Plaintiffs' demand for punitive damages, Fleet specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards, including but not limited to, those standards of limitation which arose in *BMW of North America v. Core*, 116 U.S. 1589 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

**THIRTIETH AFFIRMATIVE DEFENSE**  
**Punitive Award Barred**

146. Plaintiffs' claims for punitive damages are barred, in whole or in part, because Fleet committed no act or omission that was malicious, oppressive, willful, wanton, reckless or grossly negligent or that flagrantly disregarded the safety of any persons.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**  
**Failure To Prove Reasonable Alternative Design**

147. Plaintiffs cannot establish that any reasonable alternative design would have rendered the product safer overall, and that the failure to adopt a reasonable alternative design rendered Fleet Phospho-soda, in any of its forms, not reasonably safe, in accordance with Section 2(b) of the Restatement (Third) of Torts: Product Liability.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**  
**Failure To Prove Reasonable Alternative Warnings**

148. Plaintiffs cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risk of harm posed by Fleet Phospho-soda, in any of its forms, would have rendered the product safer overall, and that the failure to adopt a reasonable alternative instructions or warnings rendered Fleet Phospho-soda, in any of its forms, unreasonably safe, in accordance with Section 2(c) of the Restatement (Third) of Torts: Product Liability.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**  
**General Denial**

149. Fleet denies any paragraph or any portions of any paragraph in Plaintiffs' Complaint not previously referred to herein.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**  
**Constitutional Defenses**

150. The statutes of any state which authorize the imposition of aggravated, exemplary or punitive damages are contrary, by their express terms and as they may be applied to Fleet, to the Constitution of the United States and/or Constitution of the state whose law is deemed to apply and are therefore void inasmuch as said statutes deny Fleet equal protection of the law by providing fewer protections for civil litigants than the criminal statutes which provide for the imposition of monetary fines. Said statutes further are in violation of the Constitution of the United States and of the applicable state constitution inasmuch as they purportedly permit the deprivation of property without due process of law and allow for the imposition of an excessive fine.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**  
**Preemption**

151. Plaintiffs' claims are barred in whole or in part to the extent that the United States Food and Drug Administration required the use of professional labeling and restricted professional use warnings with regard to the consumer packaging and labeling.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**  
**Misrepresentations to FDA**

152. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**  
**State Preemption**

153. Plaintiffs' common law claims are preempted by the applicable state's product liability and/or tort reform statute.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**  
**Defenses Available Under State Law**

154. Fleet is entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute, including those relating to consumer protection, of any other state whose substantive law might control the action.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**  
**Attorney Fees**

155. To the extent Plaintiffs request attorneys' fees, such request is improper under the applicable law.

**FORTIETH AFFIRMATIVE DEFENSE**  
**Prejudgment Interest**

156. Fleet further pleads that to the extent any award of prejudgment interest is sought on future damages, such an award violates the due process clause of the United States Constitution and the corresponding portions of the Constitution of any state whose laws might be deemed controlling in this action.

**FORTY-FIRST AFFIRMATIVE DEFENSE**  
**Additional Defenses**

157. Fleet reserves the right to amend this Answer to assert additional affirmative defenses as discovery and information warrant.

**FORTY-SECOND AFFIRMATIVE DEFENSE**  
**General Denial**

158. Fleet denies any paragraph or any portions of any paragraph in the Complaint not previously referred to herein.

**WHEREFORE**, Defendant C.B. Fleet Company, Inc., respectfully requests that the Court dismiss Plaintiff's Complaint with prejudice, at Plaintiffs' costs, and for such other relief as this Court may deem just and proper.

Respectfully submitted,

/s/ Michael L. Snyder

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 21st day of January, 2010, a true and correct copy of Master Answer and Affirmative Defenses was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Michael L. Snyder  
*Defendant's Liaison Counsel*